EXPRESSION ANALYSIS

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Division of Documents Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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To whom it may concern:

At the DIA meeting last month in Washington DC, the FDA specifically requested comment on laboratory qualifications/requirements for processing genomic data. Within the November 2003 Draft Guidance for Industry for Pharmacogenomic Data Submissions, Section IV, Subsection D addresses the question of the need for compliance with the regulations stipulated in 21 CFR Part 58.

The laboratory qualifications for the generation of genomic data to be submitted in support of pre-clinical or clinical trials are spelled out in the regulations of 21 CFR Parts 58 and 395 respectively. In the case of voluntary genomic data submissions, as no regulatory decisions will be dependent upon this data, it is unclear that any laboratory control is required. However the agency should be aware that the current procedures that generate genomic are still evolving, and that standardization is absent across the entire spectrum of the process. Consequently the value of data derived from laboratories not adhering to Governmental Regulations must be examined with the foreknowledge that substantial differences may exist across test sites, and that some reference to quality control parameters and assay performance must be explicitly stated within the submission to support conclusions based on the data.

Respectfully,

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